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Trial record **1 of 1** for: CERL080ADE10

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# Gastrointestinal and Health-related Quality of Life Outcomes in Patients With Simultaneous Pancreas-Kidney Transplants

**This study has been completed.**

**Sponsor:**
Novartis Pharmaceuticals

**Information provided by:**
Novartis

**ClinicalTrials.gov Identifier:**
NCT00267150

First received: December 16, 2005
Last updated: May 17, 2011
Last verified: May 2011
History of Changes

Full Text View | Tabular View | Study Results | Disclaimer | How to Read a Study Record

Results First Received: December 9, 2010

| | |
|---|---|
| **Study Type:** | Interventional |
| **Study Design:** | Allocation: Non-Randomized; Endpoint Classification: Safety/Efficacy Study;<br>Intervention Model: Single Group Assignment; Masking: Open Label;<br>Primary Purpose: Treatment |
| **Conditions:** | Pancreas Transplantation<br>Kidney Transplantation |
| **Intervention:** | Drug: Enteric-coated mycophenolate sodium (EC-MPS) |

## Participant Flow

Hide Participant Flow

**Recruitment Details**

| **Key information relevant to the recruitment process for the overall study, such as dates of the recruitment period and locations** |
|---|
| No text entered. |

**Pre-Assignment Details**

| **Significant events and approaches for the overall study following participant enrollment, but prior to group assignment** |
|---|
| No text entered. |

**Reporting Groups**

| | **Description** |
|---|---|
| **Enteric Coated Mycophenolate-sodium** | Enteric coated tablets of mycophenolate-sodium taken orally twice a day for 6-8 weeks. |

**Participant Flow: Overall Study**

| | **Enteric Coated Mycophenolate-sodium** |
|---|---|
| **STARTED** | **31** |
| **COMPLETED** | **30** |
| **NOT COMPLETED** | **1** |

| | |
|---|---|
| **Adverse Event** | **1** |

## Baseline Characteristics

Hide Baseline Characteristics

**Population Description**

| |
|---|
| **Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.** |
| No text entered. |

**Reporting Groups**

| | Description |
|---|---|
| **Enteric Coated Mycophenolate-sodium** | Enteric coated tablets of mycophenolate-sodium taken orally twice a day for 6-8 weeks. |

**Baseline Measures**

| | Enteric Coated Mycophenolate-sodium |
|---|---|
| **Number of Participants [units: participants]** | **31** |
| **Age [units: years] Mean (Standard Deviation)** | **48.9 (9.5)** |
| **Gender [units: participants]** | |
| **Female** | **13** |
| **Male** | **18** |

## Outcome Measures

Hide All Outcome Measures

1. Primary: Changes in Gastrointestinal Symptom Severity and/or Health-related Quality of Life After Conversion From MMF to Enteric Coated Mycophenolate Sodium [ Time Frame: weeks 6-8 ]

| | |
|---|---|
| **Measure Type** | Primary |
| **Measure Title** | Changes in Gastrointestinal Symptom Severity and/or Health-related Quality of Life After Conversion From MMF to Enteric Coated Mycophenolate Sodium |
| **Measure Description** | The Gastrointestinal symptom rating scale (GSRS) is a 15-item instrument designed to assess the symptoms associated with common gastrointestinal disorders. The GSRS has 5 subscales (reflux, diarrhea, constipation,abdominal pain, and indigestion) producing a mean subscale score ranging from 1 (no discomfort) to 7 (very severe discomfort). The GSRS total score was computed by the mean of the subscale scores. The primary analysis examined changes from Visit 1 (baseline) to Visit 2 (6-8 weeks) by computing the difference of GSRS total score. |
| **Time Frame** | weeks 6-8 |
| **Safety Issue** | No |

**Population Description**

| |
|---|
| **Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.** |
| No text entered. |

**Reporting Groups**

| | Description |
|---|---|
| **Enteric Coated Mycophenolate-sodium** | Enteric coated tablets of mycophenolate-sodium taken orally twice a day for 6-8 weeks. |

**Measured Values**

| | Enteric Coated Mycophenolate-sodium |
|---|---|
| **Number of Participants Analyzed [units: participants]** | **30** |
| **Changes in Gastrointestinal Symptom Severity and/or Health-related Quality of Life After Conversion From MMF to Enteric Coated Mycophenolate Sodium [units: Change in Score of GSRS] Mean (Standard Deviation)** | **-0.46 (0.71)** |

**No statistical analysis provided for Changes in Gastrointestinal Symptom Severity and/or Health-related Quality of Life After Conversion From MMF to Enteric Coated Mycophenolate Sodium**

2. Secondary: Gastrointestinal Symptoms Under MMF-based Immunosuppressive Therapy [ Time Frame: week 0 ]

| | |
|---|---|
| **Measure Type** | Secondary |
| **Measure Title** | Gastrointestinal Symptoms Under MMF-based Immunosuppressive Therapy |
| **Measure Description** | Assessed by GI complications at baseline. |
| **Time Frame** | week 0 |
| **Safety Issue** | No |

**Population Description**

| **Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.** |
|---|
| Baseline population |

**Reporting Groups**

| | Description |
|---|---|
| **Enteric Coated Mycophenolate-sodium** | Enteric coated tablets of mycophenolate-sodium taken orally twice a day for 6-8 weeks. |

**Measured Values**

| | Enteric Coated Mycophenolate-sodium |
|---|---|
| **Number of Participants Analyzed [units: participants]** | **31** |
| **Gastrointestinal Symptoms Under MMF-based Immunosuppressive Therapy [units: Participants]** | |
| **Any complication** | **19** |
| **Diarrhea** | **12** |
| **Dyspepsia** | **4** |
| **Nausea** | **3** |
| **Abdominal pain/bloating/fullness** | **11** |
| **Other** | **1** |

**No statistical analysis provided for Gastrointestinal Symptoms Under MMF-based Immunosuppressive Therapy**

## Serious Adverse Events

Hide Serious Adverse Events

| | |
|---|---|
| **Time Frame** | No text entered. |
| **Additional Description** | No text entered. |

**Reporting Groups**

| | Description |
|---|---|
| **All Patients** | All patients |

**Serious Adverse Events**

| | All Patients |
|---|---|
| **Total, serious adverse events** | |
| **# participants affected / at risk** | **0/31 (0.00%)** |

## Other Adverse Events

Hide Other Adverse Events

| | |
|---|---|
| **Time Frame** | No text entered. |
| **Additional Description** | No text entered. |

**Frequency Threshold**

| | |
|---|---|
| **Threshold above which other adverse events are reported** | 5% |

**Reporting Groups**

| | Description |
|---|---|
| **All Patients** | All patients |

**Other Adverse Events**

| | All Patients |
|---|---|
| **Total, other (not including serious) adverse events** | |
| **# participants affected / at risk** | **2/31 (6.45%)** |
| **Gastrointestinal disorders** | |
| **Constipation † 1** | |
| **# participants affected / at risk** | **2/31 (6.45%)** |

† Events were collected by systematic assessment
1 Term from vocabulary, MedDRA

## Limitations and Caveats

Hide Limitations and Caveats

| **Limitations of the study, such as early termination leading to small numbers of participants analyzed and technical problems with measurement leading to unreliable or uninterpretable data** |
|---|
| No text entered. |

## More Information

Hide More Information

**Certain Agreements:**

Principal Investigators are **NOT** employed by the organization sponsoring the study.

There **IS** an agreement between Principal Investigators and the Sponsor (or its agents) that restricts the PI's rights to discuss or publish trial results after the trial is completed.

The agreement is:

☐ The only disclosure restriction on the PI is that the sponsor can review results communications prior to public release and can embargo communications regarding trial results for a period that is **less than or equal to 60 days**. The sponsor cannot require changes to the communication and cannot extend the embargo.

☐ The only disclosure restriction on the PI is that the sponsor can review results communications prior to public release and can embargo communications regarding trial results for a period that is **more than 60 days but less than or equal to 180 days**. The sponsor cannot require changes to the communication and cannot extend the embargo.

Other disclosure agreement that restricts the right of the PI to discuss or publish trial results after the trial is completed.

☑ **Restriction Description:** The terms and conditions of Novartis' agreements with its investigators may vary. However, Novartis does not prohibit any investigator from publishing. Any publications from a single-site are postponed until the publication of the pooled data (i.e., data from all sites) in the clinical trial.

**Results Point of Contact:**

Name/Title: Study Director
Organization: Novartis Pharmaceuticals
phone: 862-778-8300

**No publications provided**

| | |
|---|---|
| Responsible Party: | External Affairs, Novartis Pharmaceuticals |
| ClinicalTrials.gov Identifier: | NCT00267150 History of Changes |
| Other Study ID Numbers: | **CERL080ADE10** |
| Study First Received: | December 16, 2005 |
| Results First Received: | December 9, 2010 |
| Last Updated: | May 17, 2011 |
| Health Authority: | Germany: Paul-Ehrlich-Institut |